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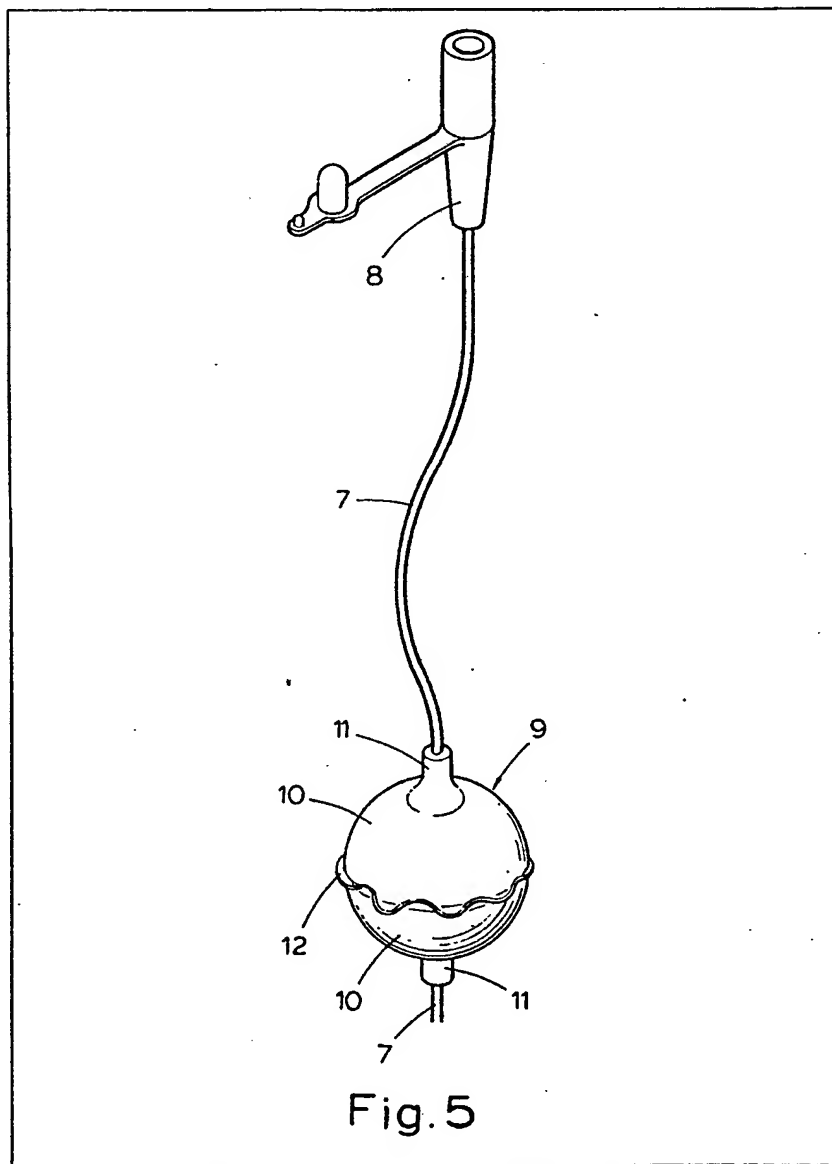
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(54) Indicating pressure

(57) The amount of pressure in a surgical device, for example a catheter, with an inflation element, for example an inflation cuff, is indicated

by a pilot balloon 9 formed from two sheets 10 arranged in face contact with each other and secured at the periphery in an air-tight manner as by a weld 12. At least one of the sheets 10 is deformable under the action of inflation pressure.



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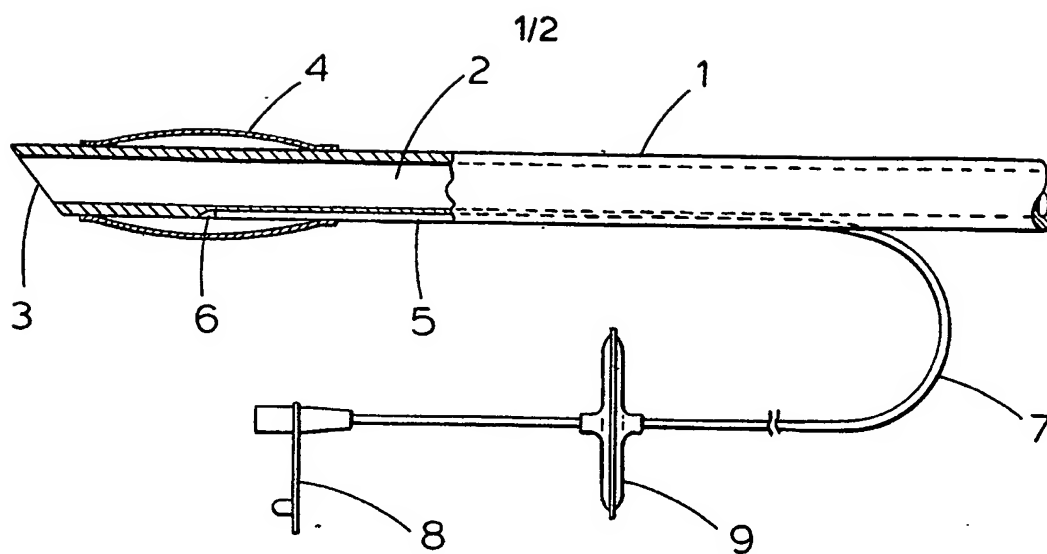


Fig. 1

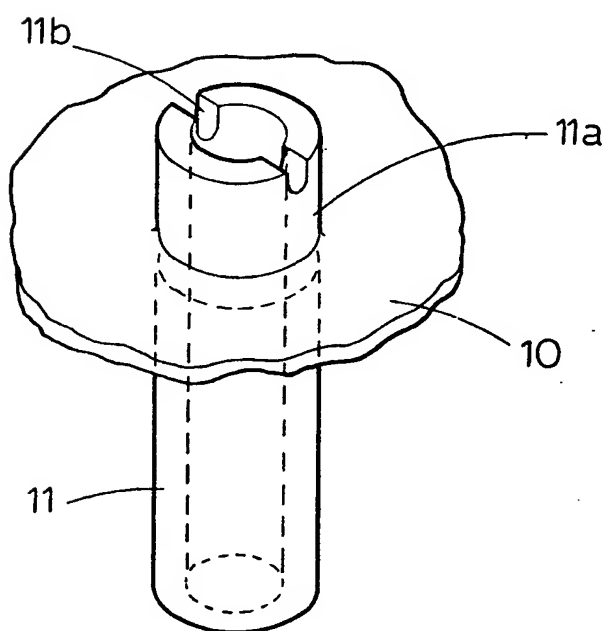
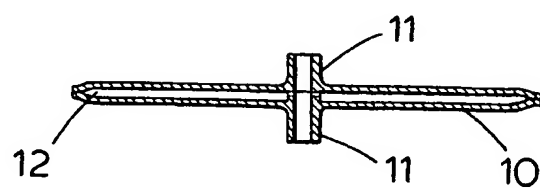


Fig. 2

Fig. 3



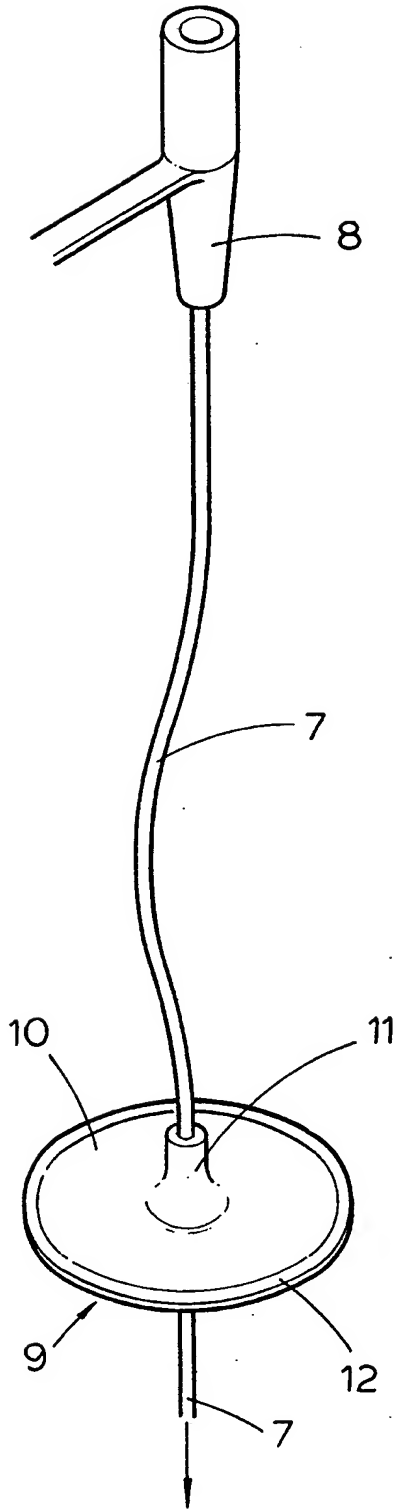


Fig. 4

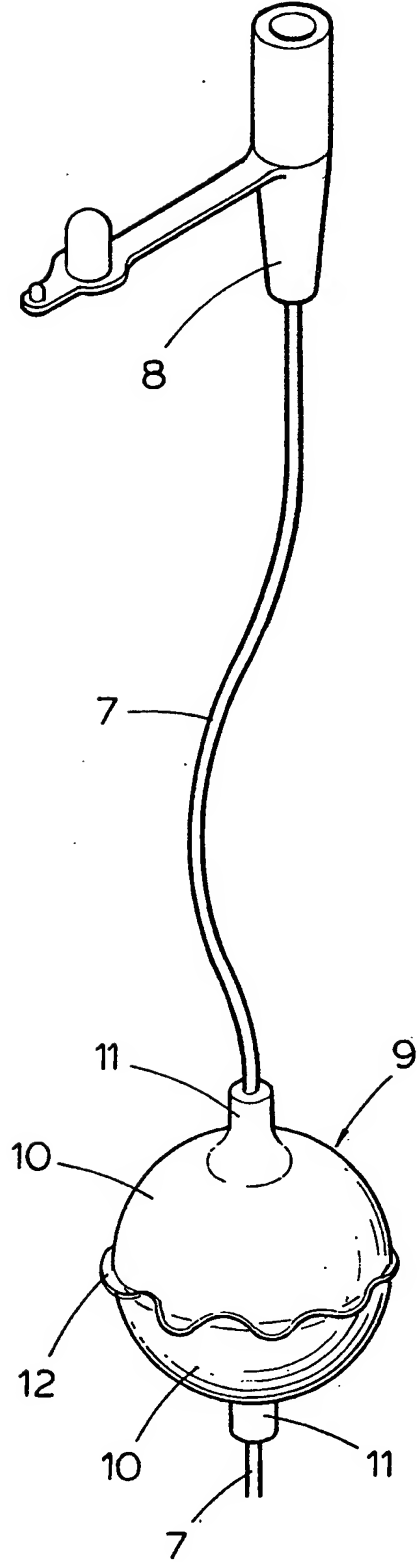


Fig. 5

SPECIFICATION **Surgical catheters**

This invention relates to surgical devices, particularly, but not exclusively, catheters.

5 Balloon catheters are well known and comprise a main tube, usually called a "shaft" through which runs a main passage or "lumen". Inlet/outlet openings lead through the shaft and communicate with the lumen near one end of the shaft, usually called the distal end, which is intended to be inserted into the patient. An inflation cuff or balloon surrounds the shaft near the distal end. This cuff can be inflated by air pressure supplied to the cuff through an inflation passage or "line" running through the wall of the shaft and running into an inflation tube branching off from the shaft near the proximal end. This branch inflation tube often contains a balloon called a pilot balloon, which will be inflated when the inflation cuff is inflated so as to give an indication of the amount of inflation of the inflation cuff which is not visible, being inserted into the patient.

In a known such catheter, the pilot balloon is fabricated from sheet polyvinylchloride welded into a flat pilot balloon outline, and an extruded tube extends through the weld into and out of the pilot balloon. It is very difficult to fabricate pilot balloons of this character. Furthermore, they are not entirely reliable because inflation pressure is inclined to leak from them and this results in an unacceptably high number of rejects during manufacture. It is exceedingly important that there is no leakage from the pilot balloon. In some cases such leakage may even have fatal consequences for a patient.

An object of the invention is to provide an improved catheter of this character which is more reliable than those previously available and in which the pilot balloon will give a better indication of the inflation cuff than is the case with known catheters.

The present invention provides a surgical device comprising an inflation element which can be inflated by pressure supplied through an inflation line containing a pilot balloon, wherein the pilot balloon comprises two sheets of material arranged in face contact with each other and secured together at the periphery in an airtight manner, at least one of the sheets being deformable under the action of inflation pressure inside the pilot balloon, the pilot balloon being connected with the inflation line so as to be responsive to pressure in the said line. The surgical device may be a surgical catheter and the inflation element may be an inflation cuff surrounding a shaft of the catheter, wherein the pilot balloon comprises two sheets of flexible material arranged in face contact with each other and secured together at the perimeter in an airtight manner, the inflation line being in two parts each one of which is secured to one of the sheets of the pilot balloon and opens inside the pilot balloon. The surgical device need not, however, be

65 a catheter, but may be a device for example, a nasal plug, having an inflating component associated with a pilot balloon.

The invention is schematically illustrated in the accompanying drawings in which:

70 Figure 1 is a diagram illustrating a balloon catheter.

Figure 2 is a fragmentary perspective view illustrating part of a pilot balloon of the catheter,

75 Figure 3 is a cross-section through a pilot balloon in a deflated condition,

Figure 4 is a perspective view of a branch inflation line of the catheter showing the pilot balloon in a deflated condition, and

80 Figure 5 is a similar view showing the pilot balloon in an idealised inflated condition.

In the illustrated embodiment of the invention, a surgical catheter for endotracheal use comprises a hollow shaft 1 of thermoplastic material such as polyvinylchloride. The shaft 1 has a main passage or lumen 2 running through the shaft and opening at one end 3 intended to be inserted into the patient, this end being called the distal end. An inflation cuff or balloon 4 surrounds the shaft 1 near the distal end. This inflation cuff or balloon can be inflated by air pressure applied through a subsidiary passage or inflation line 5 running through the wall of the shaft and terminating at openings 6 beneath the cuff 4. The inflation line branches into a tube 7 near the proximal end of the shaft. This branch portion 7 of the inflation line terminates in a connector 8 arranged to receive an end of a syringe, not shown, used to inflate the cuff or balloon 4. The branch inflation line 7 includes a pilot balloon 9 which is inflatable when the cuff 4 is inflated and gives a visual and tactile indication of the amount of inflation of the cuff. The pilot balloon 9 comprises two circular sheets or discs of thermoplastic material such as polyvinylchloride. These sheets 10 have central apertures surrounded and reinforced by short integral tube portions defining bosses 11. The sheets are arranged in face contact with each other as shown clearly in Figures 3 and 4. They are sealed together at their perimeters in an air-tight manner. The sealing may be provided by a weld 12 which is preferably affected by radio frequency heating. The contacting faces of the sheets may have protuberances to ensure that the contacting faces will separate easily when the pilot balloon is inflated. Such protuberances may be conveniently provided by extending the bosses 11 to the other side of the sheet as shown to an exaggerated scale at 11a in Figure 2. The extensions 11a have grooves 11b through which air may flow. Such protuberances are not essential, but they are desirable to ensure reliability of inflation if the contacting faces are of some materials such as shiny polyvinylchloride which have a tendency to stick together. The branch inflation line 7 is in two parts and the ends of each of these two parts are welded by solvent welding to the collars 11 as clearly shown in Figure 5. When air pressure is applied through the inflation line 5, 7 to inflate the cuff 4, the pilot

balloon 9 comprising the two sheets 10 is also inflated and the balloon will have the approximately spherical configuration illustrated in Figure 5. This configuration gives a better indication of the extent of inflation of the cuff 4. beacuse the inflation line 7 is in two parts which can move apart with the sheets 10 when the pilot balloon is inflated. In addition, the weld 12 is sufficiently narrow that it can readily distort on inflation of the pilot balloon so that it will not impose forces which will adversely affect the indicating qualities of the pilot balloon. If desired the two sheets 10 have differing shades or colours to make it easier to see the degree of inflation.

15 The inflation pressure in the cuff or balloon 4 is dependent on the nature and dimensions of the material of the sheets 10 and the dimensions of the peripheral weld 12. It follows, therefore, that if these parameters are suitably selected and controlled so as to be known the visible degree of inflation of the pilot balloon 9 will give an indication of the inflation pressure in the cuff or balloon 4.

CLAIMS

25 1. A surgical device comprising an inflation element which can be inflated by fluid pressure supplied through an inflation line containing a pilot balloon, wherein the pilot balloon comprises two sheets of material arranged in face contact with

30 each other and secured together at the periphery in an air-tight manner, at least one of the sheets being deformable under the action of inflation pressure inside the pilot balloon, the pilot balloon being connected with the inflation line so as to be responsive to pressure in the said line.

35 2. A device as claimed in claim 1, wherein the device is a catheter and the inflation element is a cuff surrounding a shaft of the catheter, the pilot balloon comprising two sheets of flexible material arranged in face contact and secured together at the perimeter in an air-tight manner, the inflation line being in two parts each one of which is secured to one of the sheets and opens inside the pilot balloon.

40 3. A device as claimed in claim 1, wherein the two sheets are of flexible material and are sealed together at their perimeters in an air-tight manner, each of the sheeting having an opening surrounded by a collar and a portion of the inflation line being received in each collar and being secured thereto in an air-tight manner.

45 4. A device as claimed in either of claims 2 or 3 wherein the two sheets of material of the pilot balloon are of differing shades or colour.

50 5. A device as claimed in any one of claims 2, 3 or 4, wherein the contacting faces of the sheets have protuberances.

55 6. A surgical device substantially as described with reference to the accompanying drawings.

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